Approved Patient Information Leaflet for
Half Strength Darrows Solution with 5 % Dextrose Fresenius

SCHEDULING STATUS

S3

HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS

Solution for infusion

1,3 g potassium chloride; 2 g sodium chloride and 2,95 g sodium lactate per 1 000 ml.

Contains sugar (50 g dextrose per 1 000 ml).

Read all of this leaflet carefully before you are given HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or health care provider.

What is in this leaflet

1. What HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS is and what it is used for

The active ingredients (see **What HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS contains**) are so-called electrolytes.

An electrolyte is a compound (most soluble salts, acids and bases) that dissociates in suitable solvents, such as water. Dextrose is a carbohydrate that also provides calories.

HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS is used by your doctor to help to manage your fluid, energy and electrolyte balance.

2. What you need to know before you are given HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS

HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS should not be administered to you:

- if you are hypersensitive (allergic) to any active ingredient, maize (maize is the raw material used in the production of dextrose), or to any ingredient of HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS (listed in section 6)
- if you have very weak kidney function with a very low output of urine, or if you do not form urine at present
- if you had a major shock and renal failure after a crushing injury to skeletal muscle
- if you have blood transfusion reactions (such as fever, chills and hives)
- if your adrenal gland does not produce suitable amounts of cortisol or aldosterone, which are needed to regulate sodium amounts, potassium release and water retention
- if your doctor has told you that you have high levels of potassium in your blood (you may experience nausea, unusual weakness or tiredness and muscle weakness)
- if your doctor has told you that you have high levels of sodium in your blood (you may experience a strong feeling of thirst, weakness, nausea and loss of appetite)
- if you have abnormally high levels of chloride (you may experience unusual weakness or tiredness, muscle weakness or excessive thirst)

- if you have heart failure that is not adequetely controlled (you may experience breathlessness, unusual weakness or tiredness, and swelling of your feet, ankles or hands)
- if you have diabetes (high blood sugar) (you may experience increased thirst, urination, unusual weakness or tiredness and blurred vision)
- if you have a metabolic disorder (you may experience a lack of energy, poor appetite or stomach pain)
- if you have abnormally high levels of lactate (you may experience extreme weakness or tiredness, muscle cramps or stomach pain).

Warnings and precautions

Tell your doctor or health care provider before receiving HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS if you have any of the following medical conditions:

- heart disease or disorder
- dehydration, extensive tissue damage or severe burns
- high blood pressure
- build-up of fluid in the lungs
- kidney, liver or adrenal gland problems
- swelling of hands, ankles or feet
- diabetes (high blood sugar) or impaired glucose tolerance
- metabolic acidosis or alkalosis (abnormal blood pH)
- risk of low sodium level in your blood (hyponatraemia)
- sepsis, trauma or shock
- severely malnutrition (getting too little or too much of certain nutrients)
- vitamin B1 (thiamine) deficiency
- consuming large quantites of alcohol
- infection or any other illness

- if HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS is given to the elderly, as they are more likely to have heart, kidney, liver and other diseases or be on other medicines
- if your baby is a neonate or very small infant (less than 6 months old). Lactate-containing solutions should be administered with particular caution to neonates and infants less than 6 months of age.

Other medicines and HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor if you are taking or receiving any of the following medicines:

- chlorpropamide (used to treat diabetes mellitus type 2)
- clofibrate (used to treat high cholesterol)
- carbamazepine, oxcarbamazepine (used to treat epilepsy, fits)
- barbiturates (used to treat anxiety, sleeplessness and epilepsy)
- vincristine, cyclophosphamide, ifosfamide (used to treat multiple cancers)
- selective serotonine reuptake inhibitors (used to treat depression)
- methamphetamine (used as a recreational drug or as second-line treatment for attention deficit hyperactivity disorder (ADHD) and obesity
- stimulants such as dexamphetamine sulphate and fenfluramine hydrochloride
- pseudoephedrine (found in cold and flu medicines)
- antipsychotics (used to treat mental health problems)
- narcotics (used to treat severe pain)
- nonsteroidal anti-inflammatory drugs (NSAIDs) including aspirin (used to treat pain, swelling and other symptoms of inflammation, including arthritis)
- vasopressin (used in the treatment of gastrointestinal bleeding)

- terlipressin (used in the management of low blood pressure)
- desmopressin (to treat central diabetes insipidus and after trauma or surgery in the pituitary region)
- oxytocin (hormone to contract the uterus)
- potassium-sparing diuretics, such as amiloride, spironolactone, triamterene (used alone or with other medicines to treat oedema (fluid retention), high blood pressure or heart failure)
- angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor antagonists, or beta-blockers (used in the treatment of high blood pressure/heart conditions)
- ciclosporin, tacrolimus (used to prevent rejection of a transplanted organ)
- insulin, metformin (used to treat diabetes)
- lithium (used to treat psychiatric illnesses)
- heparin (used to prevent the forming of a blood clot)
- digoxin (used to treat heart failure)
- sodium bicarbonate (used to treat severe metabolic acidosis)
- corticosteroids (used to treat asthma, allergic rhinitis and hay fever)
- corticotropin (used to treat epileptic spasms in infants, and psoriatic arthritis, rheumatoid arthritis, ankylosing spondylitis, multiple sclerosis or lupus erythematosus in adults).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS. The safety of HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS in pregnancy and when you are breastfeeding your baby has not been determined.

HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS should be given with special caution to pregnant woman during labour, particularly if administered in combination with oxytocin, due to the risk of hyponatraemia.

Driving and using machines

Your doctor will decide when to discharge you from hospital. HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS should not affect your ability to drive a vehicle or use machines, however, ask your doctor before performing tasks requiring your attention.

HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS contains dextrose

HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS contains sugar (50 g dextrose per 1 000 ml). This should be taken into account if you have diabetes (high blood sugar).

Dextrose may be manufactured from maize. You should not receive HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE if you are allergic to maize products.

3. How HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS will be administered

You will not be expected to give yourself HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS. It will be given to you by a person who is qualified to do so.

Your doctor will monitor the glucose, sodium and electrolytes in your blood before you are being treated and during treatment with HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS, especially if you are on medicines as mentioned (see **Other medicines and HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS**).

Adults:

In adults, less than the average daily maintenance dose of potassium is given in one litre. In potassium deficiency: 70 – 80 mmol of potassium (or more) should be given daily.
Given within the vein, the maximum rate is 3 ml per minute for adults.
You should not receive more than 10 mmol of potassium per hour if large amounts are indicated, and also less to infants and children.

Infants:

After adequate hydration and kidney function are obtained by means of the initial hydrating solution, the dose is usually 80 ml per kilogram of body weight for the first 24 hours. After the first day, 22 – 53 ml per kilogram of body weight per day may be given as long as the stools remain watery. Additional fluid required daily may be provided by carbohydrate in water in amounts calculated so that the total fluid (with and without potassium) will be 150 – 200 ml per kilogram of body weight.

If you receive more HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS than you should:

Since a health care provider will administer HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the symptoms of overdosage.

If you miss a dose of HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS:

Since a health care provider will administer HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS can have side effects.

Not all side effects reported for HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS, please consult your health care provider for advice.

If any of the following happens, stop receiving HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you notice any of the following:

Unknown frequency: Hyponatraemia (low sodium levels in your blood with symptoms such as decreased ability to think, headaches, nausea (feeling sick) and poor balance). Neurological symptoms occur when sodium levels in the blood become very low and water enters the brain cells and causes them to swell. This results in increased pressure in the skull, causing hyponatraemic encephalopathy and is a medical emergency. Heart arrest (usually results from an electrical disturbance in your

heart, characterised by loss of consciousness and unresponsiveness).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Unknown frequency: Fever, chills, hyperkalaemia (high levels of potassium in your blood, characterised by muscle weakness, numbness/tingling, nausea, vomiting, irregular heartbeat and shortness of breath), hyperchloraemic acidosis (too much acid in your body).
Fluid and electrolyte disturbance (characterised by irregular/fast heart rate, unusual weakness/tiredness, fits (seizures), nausea or vomiting).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the "**Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS.

Health care providers are asked to report any suspected adverse drug reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS

- Store at or below 25 °C.
- Discard any unused portion.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS contains

The active substances are dextrose, potassium chloride, sodium chloride and sodium lactate.

Other ingredients are water for injection and hydrochloric acid (for pH-adjustment).

What HALF STRENGTH DARROWS SOLUTION WITH 5 % DEXTROSE FRESENIUS looks like and contents of the pack:

A clear colourless to light straw-coloured solution.

200 ml, 500 ml and 1 000 ml in PVC bags or **free***flex*® (non-PVC) bags.

Not all pack sizes and container systems may be marketed.

Holder of Certificate of Registration and Manufacturer:

Fresenius Kabi Manufacturing SA (Pty) Ltd

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